

Translation

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference LTS 2002/108 PCT-FI	<b>FOR FURTHER ACTION</b> See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/EP2003/009911	International filing date (day/month/year) 06 September 2003 (06.09.2003)	Priority date (day/month/year) 16 September 2002 (16.09.2002)
International Patent Classification (IPC) or national classification and IPC B65B 9/02		
Applicant LTS LOHMANN THERAPIE-SYSTEME AG		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets, including this cover sheet.

☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of \_\_\_\_\_ sheets.

3. This report contains indications relating to the following items:

I ☒ Basis of the report

II ☐ Priority

III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

IV ☐ Lack of unity of invention

V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

VI ☐ Certain documents cited

VII ☐ Certain defects in the international application

VIII ☐ Certain observations on the international application

Date of submission of the demand 10 March 2004 (10.03.2004)	Date of completion of this report 10 November 2004 (10.11.2004)
Name and mailing address of the IPEA/EP	Authorized officer
Facsimile No.	Telephone No.

# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.  
PCT/EP2003/009911

## I. Basis of the report

### 1. With regard to the elements of the international application:\*

- ☐ the international application as originally filed
- ☒ the description:  
 pages \_\_\_\_\_ 1-10 \_\_\_\_\_, as originally filed  
 pages \_\_\_\_\_, filed with the demand  
 pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_
- ☒ the claims:  
 pages \_\_\_\_\_ 1-8 \_\_\_\_\_, as originally filed  
 pages \_\_\_\_\_, as amended (together with any statement under Article 19  
 pages \_\_\_\_\_, filed with the demand  
 pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_
- ☒ the drawings:  
 pages \_\_\_\_\_ 1-2 \_\_\_\_\_, as originally filed  
 pages \_\_\_\_\_, filed with the demand  
 pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_
- ☐ the sequence listing part of the description:  
 pages \_\_\_\_\_, as originally filed  
 pages \_\_\_\_\_, filed with the demand  
 pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_

### 2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

- These elements were available or furnished to this Authority in the following language \_\_\_\_\_ which is:
- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

### 3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

### 4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages \_\_\_\_\_
- ☐ the claims, Nos. \_\_\_\_\_
- ☐ the drawings, sheets/fig \_\_\_\_\_

### 5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).\*\*

\* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rule 70.16 and 70.17).

\*\* Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement****1. Statement**

Novelty (N)	Claims	1 - 8	YES
	Claims		NO
Inventive step (IS)	Claims	1 - 8	YES
	Claims		NO
Industrial applicability (IA)	Claims	1 - 8	YES
	Claims		NO

**2. Citations and explanations**

Document D1 (DE 198 00 682 A, LOHMANN THERAPIE SYST LTS, 15 July 1999 (1999-07-15)) describes a direct precursor of the claimed subject matter and is regarded as the closest prior art. Unlike in D1, in particular according to the embodiment depicted in figure 2, the film of active substance is fed without stresses to the packaging unit in the vertical direction. This ensures an even gentler treatment of the sensitive wafers. A person skilled in the art would not consider the remaining available prior art because it does not relate to wafers and their special conditions. The process as per claim 1 and the corresponding device as per claim 6 should therefore be recognised to involve an inventive step as a whole (PCT Article 33(3)). The dependent claims relate to special embodiments and therefore also meet these requirements.

**BOX VII****Certain defects in the international application**

The features of the preambles of claims 1 and 6 not followed by reference signs placed between parentheses (PCT Rule 6.2(b)).

**BOX VIII****Certain observations on the international application**

In claim 1, a process step is defined as "the front end of the active substance film is mechanically guided without stresses...". However, this only indicates the result to be achieved, namely a stress-free guidance, without indicating the technical features which would be required to achieve this result. These would clearly be the transport of the active substance film in the vertical direction under the influence of the force of gravity; the application does not mention or suggest any other possibility. Since the subject matter for which protection is sought is not clearly defined, claim 1 does not meet the requirements of PCT Article 6.

In the device, the cutting tool must obviously be arranged after the separating roller, because otherwise the process according to the preceding claims could not be carried out. The application thus contravenes PCT Article 6 because it lacks clear indications.

**Feld Nr. VIII (III) ERKLÄRUNG: BERECHTIGUNG, DIE PRIORITÄT EINER FRÜHEREN ANMELDUNG ZU BEANSPRUCHEN**

*Die Erklärung muß dem in Abschnitt 213 vorgeschriebenen Wortlaut entsprechen; siehe Anmerkungen zu den Feldern VIII, VIII (I) bis (V) (allgemein) und insbesondere die Anmerkungen zum Feld Nr. VIII (III). Wird dieses Feld nicht benutzt, so sollte dieses Blatt dem Antrag nicht beigelegt werden.*

Erklärung hinsichtlich der Berechtigung des Anmelders, zum Zeitpunkt des internationalen Anmeldedatums, die Priorität der unten aufgeführten früheren Anmeldung zu beanspruchen, in Fällen, in denen der Anmelder nicht auch der Anmelder der früheren Anmeldung ist, oder in Fällen, in denen sich der Name des Anmelders seit der Einreichung der früheren Anmeldung geändert hat (Regeln 4.17 Ziffer iii und 51 bis.1 Absatz a Ziffer iii):

in bezug auf diese internationale Anmeldung,

LTS Lohmann Therapie-Systeme AG ist kraft des nachfolgend Aufgeführten berechtigt, die Priorität der früheren Anmeldung Nr. 60/411,269 zu beanspruchen:

LTS Lohmann Therapie-Systeme AG ist berechtigt als Arbeitgeber des Erfinders SCHÄFER, Wolfgang

LTS Lohmann Therapie-Systeme AG ist berechtigt als Arbeitgeber des Erfinders HACKBARTH, Ronald

LTS Lohmann Therapie-Systeme AG ist berechtigt als Arbeitgeber des Erfinders SAHM, Hans-Dieter

Diese Erklärung wird abgegeben im Hinblick auf alle Bestimmungsstaaten.

☐ Diese Erklärung wird auf dem folgenden Blatt fortgeführt, "Fortsetzungsblatt für Feld Nr. VIII (iii)".